

Application No.: 10/528,326
Response to Office Action dated Feb. 12, 2007
Page 6 of 8

RECEIVED
CENTRAL FAX CENTER
MAR 12 2007

REMARKS

Applicants have cancelled claims 1-30, without disclaimer or prejudice to the subject matter contained therein. Applicants add new claims 31 to 52 to more particularly and distinctly claim that which Applicants regard as their invention. No new matter has been introduced by this amendment, as support for these claims comes directly from claim 1-30. Applicants attach a table correlating the newly added claims to the originally filed claims.

Applicants hereby elect Group I directed to the polypeptide of SEQ ID NO: 2, with traverse. Applicants respectfully point out that the "Special Technical Feature" of the present invention is SEQ ID NO: 2, and all of the claims relate to this special technical feature. PCT RULE 13.2 states that Unity of Invention is satisfied if there is a technical relationship among the claimed inventions. The technical relationship is related to a "special technical feature" that each of the inventions, considered as a whole, makes over the prior art. Each of the Independent claims of the present application relates to the special technical feature SEQ ID NO: 2 and therefore form a single inventive concept. Moreover, no problem of lack of Unity arises with respect to any claims that depend from independent claims directed to the special technical feature. Claims 31-33 are directed to SEQ ID NO: 2; claims 34-37 and 52 relate to the polynucleotide encoding SEQ ID NO: 2; claims 38-40 relate to antibodies that bind SEQ ID NO: 2; and claims 41-52 relate to the use of SEQ ID NO: 2. Therefore, all of the claims have Unity of Invention and restriction of these claims is improper according to Rule 13.2.

Applicants include Annex B "Unity of Invention" and two examples of Unity of Invention taken from Chapter 10 "Unity of Invention" in the PCT Guidelines provide by

Application No.: 10/528,326
Response to Office Action dated Feb. 12, 2007
Page 7 of 8

the WIPO. Section 10.21 Example 1 and Section 10.59 Example 39 clearly illustrate that a protein and its encoding nucleic acid have Unity and the methods of manufacturing or using the protein (Substance X) have Unity. Therefore, Applicants respectfully request that the Restriction be withdrawn and all claims examined according to PCT guidelines.

Should the Office still require an Election of Species, Applicants elect SEQ ID NO: 2, with traverse. Applicants respectfully point out that under "Markush Practice" under Rule 13.2. "The requirement of technical interrelationship and the same corresponding technical feature as defined in Rule 13.2 shall be considered to be met when the alternatives are similar in nature." When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

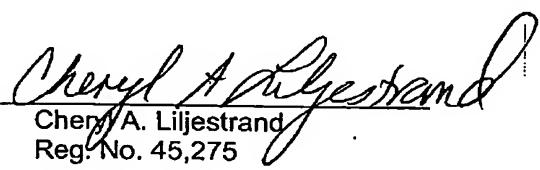
- (A) all alternatives have a common property or activity; and
- (B) (1) a common structure is present (i.e. a significant structural element is shared by all the alternatives.

In this case, all of the alternatives of claim 31 meet this criteria, and therefore, no species election under Markush Practice is required.

Respectfully Submitted,

Dated: March 12, 2007.

BY:


Cheryl A. Liljestrand
Reg. No. 45,275

Application No.: 10/528,326
Response to Office Action dated Feb. 12, 2007
Page 8 of 8

Claim Comparison Table:

| New Claim | Original Claim |
|-----------|----------------|
| 31 | 1 |
| 32 | 2 |
| 33 | 4 |
| 34 | 8 |
| 35 | 9 |
| 36 | 10 |
| 37 | 11 |
| 38 | 5 |
| 39 | 6 |
| 40 | 21 |
| 41 | 12 |
| 42 | 5 |
| 43 | 13 |
| 44 | 14 |
| 45 | 15 |
| 46 | 16 |
| 47 | 17 |
| 48 | 18 |
| 49 | 19 |
| 50 | 24 |
| 51 | 25 |
| 52 | 30 |

ANNEX B UNITY OF INVENTION

(a) **Unity of Invention.** Rule 13.1 deals with the requirement of unity of invention and states the principle that an international application should relate to only one invention or, if there is more than one invention, that the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept.

(b) **Technical Relationship.** Rule 13.2 defines the method for determining whether the requirement of unity of invention is satisfied in respect of a group of inventions claimed in an international application. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features". The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

(c) **Independent and Dependent Claims.** Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed—for example, product, process, use or apparatus or means, etc.).

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

(ii) If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

(iii) This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

(d) **Illustrations of Particular Situations.** There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

(i) combinations of different categories of claims;

(ii) so-called "Markush practice"; and

(iii) intermediate and final products.

Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2.

Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

(e) **Combinations of Different Categories of Claims.** The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,

it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.

Also an apparatus or means shall be considered to be "specifically designed for carrying out" a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

(f) **"Markush Practice."** The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

(g) Intermediate and Final Products. The situation involving intermediate and final products is also governed by Rule 13.2.

(i) The term "intermediate" is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.

(ii) Unity of invention shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) the intermediate and final products have the same essential structural element, in that:

(1) the basic chemical structures of the intermediate and the final products are the same, or

(2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

(iii) Unity of invention may also be considered to be present between intermediate and final products of which the structures are not known—for example, as between an intermediate having a known structure and a final product the structure of which is not known, or as between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there shall be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element as the final product or incorporates an essential element into the final product.

(iv) It is possible to accept in a single international application different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.

(v) The intermediate and final products shall not be separated, in the process leading from one to the other, by an intermediate which is not new.

(vi) If the same international application claims different intermediates for different structural parts of the final product, unity shall not be regarded as being present between the intermediates.

(vii) If the intermediate and final products are families of compounds, each intermediate compound shall correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

(h) As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities shall not affect the decision on unity of invention.

(i) Rule 13.3 requires that the determination of the existence of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

(j) Rule 13.3 is not intended to constitute an encouragement to the use of alternatives within a single claim, but is intended to clarify that the criterion for the determination of unity of invention (namely, the method contained in Rule 13.2) remains the same regardless of the form of claim used.

(k) Rule 13.3 does not prevent an International Searching or Preliminary Examining Authority or an Office from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fee system applicable in that Authority or Office.

(l) Examples giving guidance on how these principles may be interpreted in particular cases are set out in the PCT International Search and Preliminary Examination Guidelines.

PCT/GL/ISPE/1

Page 80

between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there must be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element as the final product or incorporates an essential element into the final product.

(d) It is possible in a single international application to accept different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.

(e) The intermediate and final products must not be separated, in the process leading from one to the other, by an intermediate that is not new.

(f) If the same international application claims different intermediates for different structural parts of the final product, unity is not regarded as being present between the intermediates.

(g) If the intermediate and final products are families of compounds, each intermediate compound must correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

AI Annex B, Part I(h)

10.19 As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities should not affect the decision on unity of invention.

Examples Concerning Unity of Invention

10.20 The application of the principles of unity of invention is illustrated by the following examples for guidance in particular cases.

Claims in Different Categories

10.21 *Example 1*

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The (method of) use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X. However, if substance X is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

10.22 *Example 2*

Claim 1: A process of manufacture comprising steps A and B.

Claim 2: Apparatus specifically designed for carrying out step A.

Claim 3: Apparatus specifically designed for carrying out step B.

Unity exists between claims 1 and 2 or between claims 1 and 3. There is no unity between claims 2 and 3 since there exists no common special technical feature between the two claims.

10.23 *Example 3*

Claim 1: A process for painting an article in which the paint contains a new rust inhibiting substance X including the steps of atomizing the paint using

PCT/GL/ISPE/1

Page 96

One possible grouping would be:

Invention 1: Method to identify compounds... (claim 1)

Invention 2: Compound X (claim 2)

Invention 3: Compound Y (claim 3)

Invention 4: Compound Z (claim 4)

10.59 *Example 39: Protein and its Encoding DNA*

Claim 1: Isolated protein X having SEQ ID NO: 1.

Claim 2: Isolated DNA molecule encoding protein X of claim 1.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The disclosure teaches that protein X is an interleukin-1, a soluble cytokine involved in the activation of lymphocytes. The disclosure also sets forth a DNA molecule having SEQ ID NO: 2 that encodes SEQ ID NO: 1.

There is no prior art.

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).

Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature.

If an alternative DNA claim was presented that encompassed a DNA molecule that did not encode protein X, some Authorities might find that the claims did not share the same or corresponding technical feature and therefore lacked unity. Examples of such a claim follow:

Isolated DNA molecule encoding protein X, or a DNA fragment thereof.

Isolated DNA molecule having SEQ ID NO: 2, or DNA molecules which hybridise to SEQ ID NO: 2 under stringent conditions.

If prior art existed teaching either protein X or the DNA encoding protein X, some Authorities might find that the same or corresponding technical feature did not make a contribution over the prior art, that is, was not a special technical feature, and therefore unity was lacking (*a posteriori*).

Process at the International Search Stage

Invitation to Pay Additional Fees

Article 17(3)(a); Rules 16, 40.2, 40.3, 42

10.60 After deciding that lack of unity exists, except in the circumstances described in paragraphs 10.64 and 10.65, the International Searching Authority informs the applicant of the lack of unity of invention by a communication, preceding (but see paragraph 10.61, below) the issuance of the international search report and written opinion of the International Searching Authority, which contains an invitation to pay additional fees (Form PCT/ISA/206). This invitation specifies the reasons (see paragraph 10.63) for which the international application is not considered as complying with the requirement of unity of invention, identifies the separate inventions and indicates the number of additional search fees and the amount to be paid. The International Searching Authority cannot consider the application withdrawn for lack of unity of invention, nor invite the applicant to amend the